Nasal High-Flow Therapy to treat COPD exacerbations: a matter of monitoring and controlling settings?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON52864

Source
ToetsingOnline

Brief title
High-TeC

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Emphysema; Bronchitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Fisher & Paykel Ltd. ,Longfonds;PPP samenwerking,Vivisol BV Nederland

Intervention

Keyword: COPD, Exacerbation, Nasal High Flow

Outcome measures

Primary outcome

Health-Related Quality of Life

Secondary outcome

1. Treatment failure of nHFT, defined as death, need for intensive care admission for respiratory failure, need for (non)-invasive mechanical ventilation, during the study period, in patients randomised to nHFT. Participants will be asked for separate informed consent to monitor treatment failure after the formal study period in order to monitor long-term effects.

2. Hospital length of stay of the index admission, readmissions, readmission characteristics and complications. Participants will be asked for separate informed consent to monitor readmissions after the formal study period in order to monitor long-term effects.

3. Exacerbation frequency, exacerbations will be defined as periods of symptom worsening treated with oral prednisolone and/or antibiotics. Participants will be asked for separate informed consent to monitor exacerbation frequency after the formal study period in order to monitor long-term effects.

4. HRQoL and symptoms: Subjective recovery during hospitalisation and thereafter will be investigated by assessing the SGRQ,[21] the Severe

Respiratory Insufficiency (SRI) questionnaire[22], and the COPD Clinical questionnaire (CCQ)[23], the Euroquol 5-D questionnaire (EQ-5D) and the Cough and Sputum Assessment Questionnaire (CASA-Q), the Leicester Cough Questionnaire (LCQ), the modified Medical Research Council Dyspnoea Scale (mMRC), and the Work Productivity and Activity Impairment Questionnaire (WPAI).Furthermore, a questionnaire to assess the use (comfort & adverse events) of nHFT will be evaluated.

5. Gas exchange will be monitored with both arterial blood gases during spontaneous breathing at daytime and nocturnal transcutaneous monitoring while on the prescribed therapy.

6. Functional capacity will be assessed at discharge and 90 days thereafter (T1 and T3) by means of calculating daily activity level, measured with a step counter. Patients will wear the step counter for one week at home.

7. Assessment of cardiac function. An electrocardiogram (ECG) and blood pressure measurements will be performed. The N-terminal of the brain natriuretic peptide (NTproBNP) will be assessed by routine laboratory methods.

8. Compliance with the nHFT device will be read out from the compliance logs stored in the device when patients visit the outpatient clinic.

9. Cost-effectiveness will be investigated by estimating the healthcare costs

of nHFT and usual care and the HRQoL gains of the two options.

10. Mechanism of the COPD exacerbation will be assessed by peripheral blood analysis, sputum collection and nasal epithelium collection.

We will incorporate, in collaboration with the UT, a new methodology to control and monitor the effect of nHFT. To limit patient effort, we will maximize the use of non-invasive measurement methods or experimental models, which use the data of the patient trial. We will investigate patient breathing effort by surface electromyography and work of breathing analyses, output by measuring breathing patterns and lung function, in collaboration with the technical University Twente.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a disease with high morbidity and mortality worldwide. COPD exacerbations are the important contributor to disease deterioration and decrease in health-related quality of life (HRQoL). Since therapeutic options to treat exacerbations effectively are limited, many patients have persistent loss of vital functioning and suffer from frequent re-hospitalisations.
Nasal high flow therapy (nHFT) is an innovative therapy that provides humidified and heated air through a nasal cannula. Although there is some preliminary evidence that nHFT is effective in stable COPD patients, there are no data at all regarding the effectiveness of nHFT in COPD exacerbations. A key problem in the implementation of nHFT is that the underlying working mechanisms are not clear and therefore the appropriate way to apply nHFT is unknown.

Study objective

The aim of the present study is to prove efficacy of nHFT in enhancing recovery

from COPD exacerbations. We aim to improve the effectiveness of nHFT by developing new technologies to control and monitor the effect of nHFT and by providing background for optimal settings of nHFT.

Study design

The study will be designed as a multicentre randomised controlled trial, with the University Medical Center Groningen, the *Medisch Spectrum Twente*, *Albert Schweizer ziekenhuis*, Rijnstate Hospital, Noordwest Ziekenhuisgroep, Ommelander Ziekenhuis Groep (OZG), the University of Twente, Fisher and Paykel Healthcare ltd, and Vivisol Nederland BV collaborating.
One hundred fifty-eight patients hospitalised with a COPD exacerbation will be randomised to standard care or nHFT (>= 6 hours/day) during hospitalisation and the 90 days after discharge, as added to standard care. The primary outcome will be improvement in HRQoL after 90 days.

Intervention

Nasal High flow Therapy

Study burden and risks

Patients will start the intervention in the hospital. nHFT is a widely used therapy in infants and on the intensive care unit, and side-effects are usually limited. Furthermore, patients are not completely dependent on their device, as it is meant as an add-on. Therefore we do not expect serious side-effects or safety issues with regard to the therapy itself.
During hospitalisation and afterwards, during a control visit after 2 weeks and after 3 months, a number of tests will be performed, for which we carefully weighted burden to necessary data retrieval to get reliable study results and an effective therapy. Most measurements are part of regular care. In a subgroup of patients we will perform additional measurements to get more insight into working mechanisms and optimal settings, the secondary aim of our proposal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• History of COPD Global Initiative of Obstructive Lung Diseases (GOLD) stage II to IV (FEV1< 80% of predicted with an FEV1/forced vital capacity (FVC) ratio <70), with a history of at least 10 pack years smoking.
• At least 1 COPD exacerbation in the year prior to the index hospital admission (exacerbation defined as worsening of pulmonary symptoms requiring oral steroids and/or antibiotics and/or hospital admission)
• Being admitted to the hospital with a COPD exacerbation
• Written informed consent is obtained

Exclusion criteria

• No lung function data available, • The presence of another acute condition (e.g. pneumonia, acute congestive heart failure, pulmonary embolus) explaining or significantly contributing to the index admission, • Inability to comply with the tests, • The presence of another chronic lung disease (e.g. asthma, restrictive lung disease).

• Already on non-invasive ventilation or nasal high flow therapy (at home or during the exacerbation)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2018
Enrollment:	158
Type:	Actual

Medical products/devices used

Generic name:	Nasal High-Flow
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-07-2019
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-11-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-09-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-09-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL66206.042.18
Other	UMCG research register 201800398; Clinical Trials NCT03564236